510(k) SUMMARY

K070201

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87

Establishment Registration Number:	1018223
Address of Manufacturer:	Bard Medical Division C.R. Bard Inc. 8195 Industrial Blvd. Covington, Georgia 30014 USA Phone: (770) 784-6722 Fax: (770) 784-6419
Contact Person:	Michelle Gudith
Date Prepared:	June 28, 2007
Trade or Proprietary Name:	Bard® Intra-abdominal Pressure Monitoring Device
Common or Usual Name:	Cystometric tubing and infusion set; intra-abdominal pressure monitoring device
Classification Name:	Intracompartmental Pressure Monitor Product code: LXC, Unclassified
Predicate Device Identification:	Twin Star Compartment Monitoring and Fluid Collection System Bard Urodynamic Catheter Wolfe Tory AbViser™ Intra-Abdominal Pressure Monitoring Kit

AUG - 1 2007

Device Description:

The Bard® Intra-abdominal Pressure (IAP) Monitoring Device (Bard IAP Device) is composed of a tubing set used for infusing fluid into the urinary bladder through the Foley catheter sampling port. It utilizes a clamping device to occlude the urinary drainage tubing to form a fluid column through which intra-abdominal pressure is measured.

Intended use and comparison to predicate devices:

The Bard® Intra-abdominal Pressure (IAP) Monitoring Device (Bard IAP Device) is substantially equivalent to intracompartmental pressure monitoring systems, product code LXC, unclassified regulatory classification and urodynamics measurement systems, product code FEN, regulatory classification 21 CFR 876.1620.

Technological characteristics and comparison to predicate devices:

The overall design of the Bard IAP Device consisting of a set of tubing with luer connections, clamping device, and saline spike provides a means of infusing fluid into the urinary bladder for measurement of bladder pressure.

y differences in technological characteristics (e.g., design, materials) among the Bard IAP Device and the predicate devices do not raise new types of safety or effectiveness questions. Accepted scientific methods exist for assessing the effect of these new characteristics, such as performance (bench) and biological safety (biocompatibility) testing.

Summary of performance data:

The results of bench and biocompatibility testing demonstrated that the functionality, integrity, and safety of the Bard IAP Device is adequate for its intended use and support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 8, 2014

C.R. Bard Incorporated
Ms. Michelle Gudith
Director, Regulatory Affairs
8195 Industrial Boulevard
Covington, Georgia 30014

Re: K070201
Trade/Device Name: Bard® Intra-abdominal Pressure Monitoring Device
Regulatory Class: Unclassified
Product Code: PHU
Dated: June 28, 2007
Received: July 2, 2007

Dear Ms. Gudith:

This letter corrects our substantially equivalent letter of August 1, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070201

Device Name: Bard® Intra-abdominal Pressure Monitoring Device

Indications for Use:

The Bard® Intra-abdominal Pressure (IAP) Monitoring Device is intended for the monitoring of intra-abdominal pressure via a Foley urinary catheter. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS).

Prescription Use: ___X___ AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070201